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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

OAKLAND DIVISION

TRI-VALLEY CARES, MARYLIA KELLEY, JANIS KATE TURNER, and JEDIDJAH DE VRIES, Plaintiffs, v. UNITED STATES DEPARTMENT OF ENERGY, NATIONAL NUCLEAR SECURITY ADMINISTRATION, LAWRENCE LIVERMORE NATIONAL LABORATORY, Defendants.	Case No. 08-cv-1372-SBA DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

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I. INTRODUCTION

Before the Court is Plaintiffs' request for a preliminary injunction halting the ongoing operation of a Biosafety Level 3 (BSL-3) lab at the Lawrence Livermore National Laboratory (LLNL). Plaintiffs' motion should be denied.

On the merits, this is Plaintiffs' second challenge to the Environmental Assessment (EA) prepared by the Department of Energy (DOE) to evaluate the environmental impacts of the facility pursuant to the National Environmental Policy Act (NEPA), 42 U.S.C. §§ 4321-4370d. In Plaintiffs' first challenge, both this Court and Court of Appeals upheld the vast majority of the DOE's analysis, remanding the matter to the DOE only for consideration of the narrow question of whether the threat of terrorist activity required preparation of an Environmental Impact Statement. On remand, the DOE carefully considered the threat of terrorist activity and issued a Revised EA. Plaintiffs now challenge not only that analysis, but a host of issues previously rejected by this Court and the Court of Appeals. As set forth below, these claims fail.

In addition to failing to demonstrate a likelihood of success on the merits, Plaintiffs' motion must be rejected because the balance of harms favors allowing operations of the BSL-3 facility to continue. While Plaintiffs rely on an attenuated and speculative claim to harm, an injunction will cause concrete harm to the LLNL's biological security program and to the national interest.

II. FACTUAL BACKGROUND

A. Prior Litigation

On December 16, 2002, pursuant to its statutory mission to reduce the global danger from weapons of mass destruction, including biological weapons, the National Nuclear Security Administration (NNSA), an agency within the DOE, authorized the construction of a BSL-3 laboratory at LLNL. Exh. 1 at 4. Pursuant to NEPA, the DOE described the need for the BSL-3 lab and its conclusion that the lab will not have a significant impact on the environment in an EA and finding of no significant impact (FONSI).

On August 26, 2003, Plaintiffs brought suit challenging the EA in numerous regards. Dkt No. 1, Case No.03-cv-03926-SBA. On September 10, 2004, this Court issued an order granting DOE's motion for summary judgment and denying Plaintiffs' motion for summary judgment. See

Exh. 2. Plaintiffs appealed, and on October 16, 2006, the Ninth Circuit affirmed in part, and reversed in part. See Exh. 3. The Court of Appeals found that with the exception of the lack of analysis of the possibility of a terrorist attack, the DOE took "a 'hard look' at the identified environmental concerns and that the DOE's decision was fully informed and well-considered." Id. at 4. With regard to the possibility of terrorist attack, the Court of Appeals reversed on the basis of a new appellate court decision, San Luis Obispo Mothers for Peace v. Nuclear Regulatory Comm'n, 449 F.3d 1016 (9th Cir. 2006). This Court therefore remanded the case to the DOE to "consider whether the threat of terrorist activity necessitates the preparation of an Environmental Impact Statement." Dkt No. 150, Case No.03-cv-3926-SBA.

On May 11, 2007, the DOE released for public comment a draft Revised EA which addressed the impacts potentially associated with terrorist attacks. On January 25, 2008, after evaluating public comment, the DOE released a Final Revised EA and a FONSI. See Exhs. 1 and 4. BSL- 3 operations at the facility began on January 25, 2008. See Exh. 5 at ¶ 3.

B. The LLNL BSL-3 lab

DOE originally proposed the BSL-3 lab as part of the Chemical and Biological National Security Program, an initiative developed in response to the 1997 Defense Against Weapons of Mass Destruction Act, 50 U.S.C. § 2301, and designed to engage NNSA's laboratories in improving preparedness for chemical and biological attacks. Exh. 1 at 4. Congress subsequently transferred some of the NNSA's biological security mission to the Department of Homeland Security (DHS). Id. DHS is authorized to access DOE laboratory resources in furtherance of its biological security mission, and LLNL contemplates that the majority of research conducted at the BSL-3 facility be performed for the DHS. Id.

Current bioscience work at LLNL targets both the reduction of the national threat from terrorism using biological weapons and enhancement of public health capabilities. Exh. 1 at 6. For example, LLNL "has developed the Biological Aerosol Sentry and Information System ("BASIS") to aid in early detection and rapid response to biological attack." Id.

Prior to the opening of the BSL-3 lab, LLNL only maintained microbiology laboratories equipped to operate at Biosafety Levels ("BSL") 1 and 2. Exh. 1 at 7. Therefore, when research at

LLNL required use of a BSL-3 laboratory, off-site private sector and University facilities had to be used. Id. The use of off-site facilities is problematic because chances of cross-contamination and degradation of samples is increased by excessive handling and transportation, because security at off-site facilities cannot be guaranteed, and because, off-site BSL-3 laboratories are in high demand, and frequently committed to projects for other entities. Id. DOE therefore determined that future bioscience work at LLNL required the construction of an on-site BSL-3 facility. Id. at 8.

The designation "BSL-3" refers to the "Biosafety in Microbiological and Biomedical Laboratories" (BMBL) guidelines promulgated by the Centers for Disease Control and Prevention (CDC) and National Institutes for Health (NIH). Designed to standardize procedures, safety equipment and facility design to protect laboratory workers and the public, the CDC guidelines divide laboratory operations into four levels, BSL-1 to BSL-4. BSL-3 laboratories work with agents which may cause diseases with serious or lethal consequences *if untreated* and which have the potential of aerosol (airborne) transmission. There are over 1,350 BSL-3 laboratories in the United States. Id. Common examples include hospital surgical suites, laboratories associated with medical schools and university research laboratories. Exh. 1 at 6.

After identifying the need for an on-site BSL-3 lab, the EA considered a range of alternatives, see id. at 26-27, and determined that the best alternative was to use a prefabricated building installed adjacent to the existing BSL-2 facilities. Id. at 9. The 1,500 square foot lab contains three BSL-3 lab rooms, and will normally be occupied by no more than six workers. Id.

As constructed, the lab exceeds CDC/NIH guidelines. Among the safety features of the building is a High Efficiency Particulate Air-Purifying (HEPA) air filtration system, in which all laboratory room air passes through two state-of-the-art HEPA filters in series before being vented outside. Exh. 1 at 13. Each HEPA filter is a minimum of 99.97 percent efficient at removing bioagents. Exh. 1 at 43, 55. One room within the BLS-3 lab is equipped with pressurized HEPA filtered cages to handle up to 100 rodents. Exh. 1 at 15-16.

Operations at the BSL-3 lab are governed by a stringent set of guidelines and regulations. First, as noted above, the CDC and NIH have established comprehensive standards for the operation of BSL-3 labs to which the LLNL lab must adhere. Exh. 1 at 17-19. Among other things, the CDC

standards require that before infectious microorganisms may be handled, a risk analysis must be prepared, and the local medical community be informed of the agent being handled and the methods of identifying and treating the diseases associated with that agent. Exh. 1 at 18. Prior to using a CDC designated select agent, the facility must register with the CDC and demonstrate that it "meets biosafety level requirements for working with the particular biological agent." Id. at 17. The CDC periodically inspects facilities. Id. at 21.

Second, pursuant to NIH regulations, operations at the BSL-3 lab are subject to the LLNL Institutional Biosafety Committee (IBC), which includes staff members, health care providers, a DOE federal official and at least two members of the public. Exh. 1 at 5-6. All experiments with pathogens must first be reviewed and approved by the IBC. Exh. 6 at C-8. This ensures that "the public will be involved in approval of BSL-3 research and review of safety and compliance protocol[s]." Id. at C-11.

Pursuant to NEPA, the EA disclosed the environmental impacts of the proposed BSL-3 lab on a wide range of issues, including: human health (Exh.1 at 40); ecological resources (id. at 39); transportation (id. at 56); waste management (id. at 48); geology, soils and seismology (id. at 49); noise (id. at 47); and air quality (id. at 46).

In evaluating the health impacts of lab operations on laboratory personnel and the public, DOE drew from three relevant comparisons: the experience of the hundreds of CDC-registered BSL-3 laboratories, the experience of the U.S. Army's Biological Defense Research Program (BDRP) laboratories, and DOE's own experience with microbiology labs. Exh. 1 at 40-42. DOE found that since the CDC's guidelines were issued in 1974, there has been an extremely low incidence of laboratory-acquired infections in laboratories following CDC guidelines. Id. at 41. The U.S. Army's BDRP labs have a similarly impressive safety record; the Army estimates that the rate of public infection from Army microbiology between 1970 and 1989 is less than 0.001 per 1,000,000 person-years and the risk of death to a laboratory worker as 0.005 per 1,000,000 person years. Id. at 42. Finally, DOE found its own biological laboratory experience at LLNL confirms the insignificant risk of public or worker infection in CDC-registered and Army labs. In the past 20 years there have been no infections of lab personnel or the public from the operations of LLNL's

biological research facilities. Id. Nor have there been any unintentional releases of bioagents associated with LLNL biological research labs. Id. Thus, DOE concluded that there would be "no discernible public human health effect from routine BSL-3 laboratory operations at the proposed facility." Id. at 41.

In addition to evaluating normal operations, DOE carefully considered the potential impacts of abnormal events and accident scenarios through a "catastrophic release scenario" which shows the outside bounds of the impact of the accidental release of a pathogen. Id. at 51. As explained more fully below, this scenario revealed that even in the extremely unlikely event of a bioagent release, there would be no significant impact on public health and safety. Id. at 55.

Based on its consideration of all reasonably foreseeable environmental impacts, and given the proven safety record of CDC-monitored and Army BSL-3 laboratories, the safety record of existing biological operations at LLNL, and the negligible impact of even a highly unlikely "catastrophic release scenario," the DOE concluded that the BSL-3 lab would not significantly impact the human environment, and on December 16, 2002, issued a FONSI approving the lab.

On remand, the DOE carefully addressed impacts of a potential terrorist attack. The agency addressed three potential scenarios: a destructive direct attack on the facility – such as an airplane crash or explosive device– that would breach facility containment; theft of and later release of a pathogen by a terrorist; and theft of and later release by an insider with access to the facility. Exh. 1 at 57-64. With regard to a destructive direct attack, the DOE found that the impacts of such an attack were bounded by the accidental catastrophic release scenario, and would not have a significant impact on the environment. With regard to theft and later release of the a pathogen whether by terrorist or insider, the DOE found that, in light of the 1,350 other BSL-3 facilities where comparable pathogens are available, the risk of a terrorist acquiring pathogenic material is not significantly increased by the presence of such material at LLNL, one of the most secure facilities in the nation. Id. at 64. DOE issued a new FONSI on January 25, 2008.

III. STANDARD OF REVIEW

A preliminary injunction is an extraordinary remedy, the entitlement to which the plaintiff bears the burden of proving by clear and convincing evidence. See Granny Goose Foods, Inc. v.

Teamsters, 415 U.S. 423, 442 (1974). A plaintiff must show either a likelihood of success on the merits and the possibility of irreparable injury, or that serious questions going to the merits were raised and the balance of hardships tips sharply in its favor. Sun Microsystems, Inc. v. Microsoft Corp., 188 F.3d 1115, 1119 (9th Cir.1999). These two alternatives represent extremes of a single continuum rather than two separate tests. Id. Thus, the greater the relative hardship to the moving party, the less probability of success must be shown. Id. However, "[u]nder either formulation of the test, the party seeking the injunction must demonstrate that it will be exposed to some significant risk of irreparable injury." Associated Gen. Contractors of Cal. v. Coal. for Econ. Equity, 950 F.2d 1401, 1410 (9th Cir. 1991).

In addition to the balancing of the relative hardships to the parties, the Ninth Circuit directs that courts must also consider the impacts of an injunction on the public interest. Sammartano v. First Judicial Dist. Court, 303 F.3d 959, 974 (9th Cir. 2002) ("While we have at times subsumed this inquiry into the balancing of the hardships, see, e.g., Caribbean Marine Services Co. v. Baldrige, 844 F.2d 668, 674 (9th Cir. 1988), it is better seen as an element that deserves separate attention in cases where the public interest may be affected.").

The traditional equitable rules for injunctive relief are not altered by the invocation of an environmental statute such as NEPA. Both the Supreme Court and the Ninth Circuit have rejected the notion that an injunction presumptively follows the violation of environmental statutes. Amoco Prod. Co. v. Village of Gambell, 480 U.S. 531, 545 (1987) (finding the environment can be "fully protected" without the presumption that irreparable damage occurs when an agency fails to evaluate thoroughly the environmental impact of a proposed action); Northern Cheyenne Tribe v. Norton, 503 F.3d 836, 844 n.30 (9th Cir. 2007) ("The dissent argues a NEPA violation requires an injunction prohibiting all action pending NEPA compliance. On the contrary, there is no such absolute rule."). Similarly, there is no presumption that environmental harm should outweigh other harms to the public interest. Fund for Animals, Inc. v. Lujan, 962 F.2d 1391, 1400 (9th Cir. 1992).

IV. LEGAL BACKGROUND

NEPA is a procedural statute which obligates federal agencies to disclose the environmental consequences of a proposed action before a decision is made. NEPA does not require an agency to

choose a particular course of action, but only to take a hard look at its action and disclose the impacts to the public. Marsh v. Oregon Natural Res. Council, 490 U.S. 360, 371 (1989).

For "major Federal actions significantly affecting the quality of the human environment," NEPA requires federal agencies to prepare a detailed Environmental Impact Statement (EIS). 42 U.S.C. § 4332(2)(C). NEPA also permits an agency to prepare a concise Environmental Assessment (EA) to determine whether an action is one requiring an EIS. 40 C.F.R. § 1508.9; 10 C.F.R. § 1021.321. If the EA reveals the proposed action will not have a significant impact on the environment, the Agency may complete its NEPA obligations by issuing a "finding of no significant impact" (FONSI), and need not prepare a full EIS. Here, the DOE prepared an EA which took a hard look at all reasonably foreseeable impacts of the proposed BSL-3 lab, and properly concluded the lab will not have significant environmental impacts.

Plaintiffs' NEPA challenge is reviewed under the narrow and highly deferential standard of review set forth in the Administrative Procedure Act (APA), 5 U.S.C. §§ 701-706. Under the APA the Court's review is limited to a determination of whether the agency acted in a manner that was "arbitrary, capricious, an abuse of discretion or otherwise not in accordance with the law." 5 U.S.C. §706(2)(A). The agency action under review is provided a presumption of administrative regularity, thus a presumption that the agency has acted in accordance with the law. Citizens to Preserve Overton Park v. Volpe, 401 U.S. 402, 415 (1971).[1]/

V. ARGUMENT

A. Plaintiffs Have not Demonstrated a Likelihood of Success on the Merits.

1. DOE Properly Addressed Terrorism Risks on Remand.

Plaintiffs first assert that the DOE failed to adequately address the question of whether the threat of terrorist activities requires preparation of an EIS. Pl. Br. at 13. Plaintiffs have no likelihood of success on this claim. As set forth below, the DOE carefully evaluated of the threat of terrorist

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[1]/ Ultimately judicial review will be based on (and limited to) the administrative record before the agency. Florida Power & Light Co. v. Lorion, 470 U.S. 729, 743 (1985). Because that record has not yet been compiled and filed with the Court, to facilitate the Court's review of Plaintiffs' motion for preliminary injunction, Defendants have attached as exhibits several documents which will ultimately be included in the record.

activities and reached the determination that preparation of an EIS was not necessary.

a. Breach of Containment from Terrorist Attack

DOE first considered the impact of a breach of all facility containment systems caused by an event such as a suicide airplane crash or an explosive device delivered by a vehicle or individual on foot. Exh. 1 at 59. As the EA explains, several factors severely limit the consequences of such an event. First, during routine lab operations, very limited quantities of biological agents would be in use – usually only enough to begin cultures in a petri dish – and such agents would typically be handled in a liquid or solid medium, so that if spilled, very few organisms would be released to the air. Id. When not in use, organisms are stored in 2 mL sealed plastic vials and locked in -80°C freezers. Exh. 6 at C-22. So for any quantity of a pathogen to be released, the lab itself, the freezers and the individual containment vials would all have to be breached, and frozen material converted to a dispersible form. See id. at C-24. Even if the structure were breached and materials in a dispersible form released, the negative air pressure in the building means that air would be drawn *into* the building and through the HEPA filtration system instead of inside air escaping unfiltered. Exh. 7 at ¶ 6. Second, the EA explains that the fire resulting from an airplane crash or explosive device of the magnitude necessary to breach containment would itself kill BLS-3 organisms quickly. Exh. 1 at 59.[2]/ Finally, in the highly unlikely event that a bioagent is released, microorganisms are generally rendered innocuous by exposure to outside conditions, in particular exposure to sunlight and dehydration. Id.

The EA explains that these factors would substantially reduce the number of microbes released as a result of a direct attack within minutes, and that the impacts of a facility breach caused by a direct terrorist act, such as a plane crash, would be no greater than the impacts addressed in the accident based "catastrophic release scenario" included in the EA. Exh. 1 at 59.

The "catastrophic release scenario" in the EA was designed to evaluate the outside bounds of the impact of an accident-based release of a dangerous bioagent. In formulating the scenario, triggering events such as earthquakes, explosion, fire or airplane crash were all considered. Exh.

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[2]/ For example, *Bacillus anthracis* spores are sterilized in 30 seconds at 200°C. Exh. 6 at C-22. In comparison, the flame temperature for gasoline in a "open pool" fire is 1,026°C. Id.

1 at 51. However, because microorganisms are generally rendered innocuous by high temperatures, fire, and sunlight, DOE determined such events would reduce, rather than enhance, the consequences of a release. Id. Thus, after consideration of numerous scenarios, DOE determined the most appropriate release scenario was one that has been used by the U.S. Army in conducting NEPA analyses of its own biological research labs. Id. at 52.

The U.S. Army's "maximum credible event" modeled a scenario in which a portion of a liter of *C. burnetii*, which causes Q-fever, is accidentally aerosolized and released within the lab, resulting in the production of almost 10 billion airborne human infective doses (HIDs). Id. at 54. *C. burnetii* was chosen as a representative of all types of BSL-3 microorganisms because it poses a high human health risk, is "highly durable, infectious, and transmissible, and has excellent environmental sustainability." Id. at 53. The Army then modeled the plume of HIDs as it moved through the lab and outside via the ventilation system. Id. at 54. For conservative results, the Army assumed the lab had only one HEPA filter operating at only 95 percent effectiveness. Id. The Army concluded the chance of public exposure to even a fraction of one HID was extremely remote; at a distance of only 2 meters from the building vent, one liter of air would contain less than 1 HID, and 128 feet from the vent, one liter of air would contain less than 1/100th of an HID. Id. at 54.

DOE found that the chances of exposure at LLNL were even more remote than those modeled by the Army. Id. at 54-55. The Army scenario assumes one HEPA filter that is only 95 percent effective. The LLNL BSL-3 lab, however, filters all room air through two HEPA filter banks, each of which is at least 99.97% effective. Id. at 55. The Army scenario also assumes a lab in close proximity to the public, but the LLNL BSL-3 is one-half mile from the nearest public area. Id. at 52-53. Finally, the Army scenario assumes lower wind speeds than are prevalent at LLNL, and higher wind would decrease airborne concentrations more quickly. Id. Based on this analysis, the DOE concluded that even under a highly unlikely catastrophic release, there would be no significant impact on public health or safety.

The lack of any significant impact on public health is underscored by the fact that all of the bioagents to be used in the BSL-3 facility cause diseases for which treatment or inoculation is available. Id. at 60. LLNL has briefed local health care providers, so that the consequences of any

release would be mitigated by inoculation and treatment of exposed individuals. Id.

Finally, the EA notes that the probability of such a successful terrorist attack on the facility is mitigated by the extensive security measures in place at LLNL and the BSL-3 facility itself. Id. at 60-61. Unlike the majority of the 1,350 BSL-3 labs nation-wide, which are mostly academic or clinical facilities, the LLNL site is protected by extensive physical security. LLNL is surrounded by a patrolled security fence with badge-identification required for entry. Id. at 61. LLNL is protected by its own security force; which includes an armed emergency response force. Id. In addition to LLNL security, access to the BSL-3 facility itself is limited to employees registered with the CDC and screened by LLNL. Id. Further, access to individual lab rooms within the building is limited to staff members approved to work during specific shifts, and all lab room are equipped with motion sensors. Id. Finally, within the lab, select agents are kept in locked freezers when not in use. Id.

In addition to the physical security described above, DOE has prepared a Biological Risk and Threat Assessment (BRTA) for the LLNL BSL-3 facility, which examined the potential vulnerability of the facility to terrorist attacks and security countermeasures to such threats. Exh. 1 at 61. Based on the BRTA, the DOE also prepared the LLNL Select Agents and Toxins Security Plan which sets out a protection program for LLNL's select agent use and storage areas. Id.

Thus, DOE concluded that the chance of a terrorist attack resulting in a breach of facility containment and the release of a pathogen was exceedingly remote. However, if such a breach were to occur, the resulting release would fall within the bounds of the existing catastrophic release scenario, and would not have a significant impact on human health or the environment.

b. Theft and Release of a Pathogen by a Terrorist

The DOE next considered the theft and subsequent release of a pathogen by a terrorist. Exh.1 at 60. The EA explains that the types of pathogenic organisms which would be sought by terrorists are widely available from sources other than the LLNL BSL-3 lab. Not only do hundreds of BSL-3 facilities in the United States regularly handle and store these substances, but many are

widely available from environmental sources. Id. at 62.[3]/ Thus, a terrorist seeking such organisms would be able to find them in any of hundreds of BSL-3 labs nationwide which are less secure than the LLNL facility, or from numerous unguarded natural sources. Based on the wide availability of such materials, DOE concluded that the proposed facility at LLNL would not have a significant impact on the "avenues already available to a terrorist for obtaining pathogenic materials or measurably increase the likelihood of this type of malicious act." Id. at 63.

DOE's conclusion regarding potential impacts of the theft and release of a pathogen from the LLNL facility is reasonable. Given the wide availability of potentially dangerous bioagents, the operations of a single facility within the highly secure LLNL complex will have no significant impact over the status quo. Where the proposed action does not significantly alter the status quo, it does not have a significant impact under NEPA. Burbank Anti-Noise Group v. Goldschmidt, 623 F.2d 115, 116 (9th Cir.1980)(holding that an EIS is not required when "the proposed federal action will effect no change in the status quo.").

c. Covert Theft and Release of a Pathogen by an Insider.

Finally, DOE considered the possibility of the covert theft and subsequent release of a pathogen by an employee with access to the facility. Exh. 1 at 63-64. DOE first notes that numerous safeguards and screening protocols are in place to insure that employees will not remove pathogens from the facility. Id.[4]/ DOE then acknowledges that in the unlikely event that a pathogen is removed and released, the impacts could be dramatic, as evidenced by the 2001 anthrax release. Id. However, as with the theft by a terrorist scenario, from a NEPA perspective, the incremental increase in risk from this single facility in light of the 1,350 facilities nation-wide, does not a represent a significant change from the environmental status quo.

2. Plaintiffs Fail to Demonstrate DOE's Evaluation of Terrorist Attacks is Arbitrary and Capricious.

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[3]/ See Exh. 1 at 62 (describing the environmental sources of the organisms that cause Anthrax, Valley Fever, Hantavirus, Plague and Rabbit Fever).

[4]/ For example, personnel with access to select agents must pass LLNL's Select Agent Human Reliability Program (SAHRP), which includes screening for physical, mental and personality disorders, alcohol and drug abuse, and any other conditions that may be a security risk. Exh. 1 at 65.

Plaintiffs bring a hodgepodge of complaints about the DOE's evaluation of the potential impacts of terrorist attacks. None of Plaintiffs' assertions, whether considered individually or together, demonstrate DOE's evaluation is arbitrary or capricious.

Plaintiffs first question DOE's methodology in examining the impacts of a direct terrorist attack resulting in a breach of containment, asserting, on the basis of selective quotations from DOE NEPA guidance, that an accident scenario should not be used to address intentional destructive acts. Pl. Br. at 13. Contrary to Plaintiffs' characterization, the cited DOE guidance actually explains that an accident based scenario "may be appropriate for many, if not most situations where the potential sabotage or terrorist scenarios and the accident scenarios involve similar physical initiating events or forces (e.g. fires, explosions, drops, punctures, aircraft crashes)," and encourages decision makers to "explicitly consider whether the accident scenarios are truly bounding of intentional destructive acts." See Pl. Exh. 13 at 2.[5]/ Here, the DOE made precisely such a determination and found that its catastrophic release accident scenario–which bounds breach events such as a plane crash– was appropriate to bound a breach event caused by a direct terrorist attack by airplane crash or explosives. Exh. 1 at 59-60. Because the accident scenario and the direct terrorist attack scenarios cover "similar physical initiating events," this analysis is imminently reasonable.

Plaintiffs also erroneously claim that DOE's use of a bounding analysis was contrary to DOE NEPA guidance. Pl. Br. at 13. To the contrary, the cited guidance merely compares the merits of bounding analyses with other scenarios. Of note, it suggests that a bounding analysis may be appropriate in circumstances –such as the instant case– where there is "analytical uncertainty." Pl. Exh. 16 at 3. In fact, a portion of the guidance omitted by Plaintiffs *recommends* use of a transportation accident scenario to bound the impacts of a terrorist attack on the transportation of nuclear waste. See Exh. 8 at 22.[6]/

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[5]/ Moreover, a portion of the guidance Plaintiffs omit explicitly indicates that "the consequences of an act of sabotage or terrorism could be discussed by a comparison to the consequences of a severe accident because the force that could result in a release of radioactive or hazardous material would be similar to those considered in accident analyses." Exh. 8 at 20.

[6]/ While DOE clearly complied with the cited guidance, internal agency guidance documents not issued pursuant to notice and comment rulemaking –like those cited– are not legally enforceable. Western Radio Serv. v. Espy, 79 F.3d 896, 901 (9th Cir. 1996).

In addition to criticizing DOE's choice to use a bounding analysis, Plaintiffs also proffer a series of complaints about the maximum credible event scenario itself, none of which demonstrate that its use was arbitrary or capricious. Pl. Br. at 14. First, Plaintiffs criticize the scenario's assumption that air passes through the facility's HEPA filters before being released outside, because they believe (without citation to authority) that a breach in the facility would result in air passing directly outside. Pl. Br. at 14. To the contrary, in the event of a breach, the facility's negative air pressure system would draw air *into* the lab rather than allowing air inside to escape unfiltered. Exh. 7 at ¶ 6; Exh. 1 at 17; Exh. 6 at C-5. Plaintiffs also criticize the assumption that released bioagents will be neutralized by heat and outside conditions, based on the fact that "weaponized" bioagents may be spread by explosive munitions. Pl. Br. at 14.[7/] The LLNL BSL-3, however, will not contain "weaponized" or "milled" biological agents that can be spread in this manner. Exh. 6 at C-23.

Plaintiffs speculate (again without citation) that DOE's breach scenario is "improbable" because a terrorist would "attempt to lightly damage the facility so as to result in a loss of containment and release of pathogenic material" without an explosion and fire which would innoculate the agents. Pl. Br. at 15. The question of the most likely attack scenario is a matter of expertise in which the Agency's experts are due deference. National Ass'n of Home Builders v. Norton, 340 F.3d 835, 843 (9th Cir. 2003) (noting that courts defer to agency's reliance of the reasonable opinions of its own qualified experts). However, if the Court chooses to engage in Plaintiffs' speculation over what a terrorist is likely to do, the flaw in Plaintiffs' "light damage without a fire" scenario is that it fails to proffer an event of sufficient magnitude to breach the building as well as the locked freezers and individual plastic vials. The DOE's assumption that any direct attack severe enough to compromise these multiple layers of containment would also involve explosion and fire is a reasonable one.

Plaintiffs criticize the DOE's statement that medical treatment will be available to the local community in the event of a pathogenic release. Pl. Br. at 15. This critique misunderstands the role of medical treatment in the NEPA analysis. DOE's finding of no significant impact does not depend

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[7/] Plaintiffs' basis for this assertion includes inadmissible hearsay statements from plaintiff Marylia Kelley. Pl. Exh. 2 at¶ 39.

on medical treatment being immediately available. As noted above, the DOE found that in the unlikely event of a release, infectious doses drop to less than .01 doses per liter of air within 128 feet of the facility, so members of the public would have "a very low likelihood of being exposed to even a small fraction of one [infectious dose]." Exh. 1 at 55. Thus, the fact that the agents used in the facility are all amenable to medical treatment, and local medical providers have been briefed on their treatment provides added assurance that a release will not have significant impacts, but it is not the basis for that finding. Exh. 1 at 60. Plaintiffs' unsupported allegation that the BSL-3 lab might release agents that have been genetically altered to make antibiotics ineffective is also off base. Such work is closely regulated, and any experiment proposing to transfer a drug resistant trait to a microorganism requires specific approval by the NIH. Exh. 9 at Section III-A-1 & III-A-1-a.

Finally, Plaintiffs assert –relying on the non-expert declaration of a named plaintiff – that a release would cause cessation of operations at LLNL, evacuation of local residents, closure of I-580, and "unprecedented economic disruption throughout the San Francisco Bay Area" and that such impacts should have been addressed in the EA. Pl. Br. at 16. This allegation is baseless. As noted above, the DOE reasonably concluded that in the event of a bioagent release, the concentration of infectious doses would be negligible within 128 feet of the release. Thus, there would be no need to evacuate the community or close highways, and no reason to speculate about the environmental impacts of such actions. Presidio Golf Club v. Nat'l Park Serv., 155 F.3d 1153, 1163 (9th Cir. 1998) (agencies "need not consider potential effects that are highly speculative or indefinite") (citations omitted).

Finally, Plaintiffs do not seriously contest DOE's evaluation of the impacts of the theft and release of a bioagent by a terrorist or insider. In particular, Plaintiffs do not challenge DOE's conclusion that given the number of BSL-3 facilities, the incremental change in the risk of a theft and release incident does not constitute a significant environmental impact. Plaintiffs' sole criticism of the theft event analysis is to assert that the availability of pathogenic materials from natural sources does not reduce the likelihood of an attempt to steal such materials from the LLNL BSL-3 because the facility may hold genetically modified agents or agents with "demonstrated human virulence" unavailable in the environment and a quantity of agents not easily collected in nature. Pl.

Br. at 16. A dispute over whether a terrorist would prefer to attempt to steal from a heavily guarded federal facility or to collect samples from unguarded domestic livestock operations, is a question of expertise as to which DOE is entitled to rely on its expertise in biosecurity issues. National Ass'n of Home Builders, 340 F.3d at 843 (judicial deference to agency expertise is appropriate); Marsh, 490 U.S. at 373 (an agency is entitled to rely on the reasonable opinions of its own experts even if, "as an original matter, a court might find contrary views more persuasive"). More to the point, however, Plaintiffs' narrow critique ignores the fact that DOE's determination that the increased risk of a theft and release incident posed by this facility is not significant is based not only on the availability of pathogenic agents from natural sources, but on the fact that these substances are also available from hundreds of relatively unguarded BSL-3 facilities nationwide.[8]/

In sum, DOE took a hard look at impacts of multiple terrorist attack scenarios, and reached the reasonable conclusion that those risks do not require preparation of an EIS. Plaintiffs fail to show this conclusion is arbitrary and capricious.

B. Plaintiffs Have Not Demonstrated Any Likelihood of Success on their Claim that the Agency Should have Prepared an EIS.

Plaintiffs' second claim is that under CEQ's "significance" factors, 40 C.F.R. § 1508.27, the DOE was required to prepare an EIS. Pl. Br. at 17. These claims– which are largely attempts to revisit claims rejected in Plaintiffs' prior challenge– all fail. The DOE reasonably concluded the LLNL BSL-3 would not have significant environmental impacts, and thus preparation of an EIS was not necessary.

1. The "context" surrounding the BSL-3 Lab does not require an EIS

Among the factors to be considered in the determination of whether a proposal's impacts are significant is their "context." 40 C.F.R. § 1508.27 (a). With regard to context, Plaintiffs assert that the impacts of the proposed facility are rendered significant by the fact that LLNL is close to Highway 580 and the San Francisco Bay Area. Pl. Br. at 17. This claim fails.

First, with regard to any pathogen release except one caused by terrorist act, this Court

[8]/ There is no difference in kind or concentration between the agents that may be used at the LLNL BSL-3 and those used at other BSL-3 facilities. Exh. 7 at ¶ 9.

previously reviewed and upheld DOE's conclusion that a release would not have significant impacts on the human environment. Exh. 2 at 13. This Court explicitly considered and rejected the claim that the proximity of the LLNL to Highway 580 and the population of the Bay Area rendered the impacts of the facility significant. Id. at 11-12. This analysis was upheld by the Court of Appeals, and is no basis for relitigating it here.[9]/ Exh. 3. However, should the Court wish to consider the question again, the DOE's accidental release scenario makes clear that human infectious doses would be reduced to negligible levels within hundreds of feet of the facility; and would certainly not cross the ½ mile distance between the lab and the nearest public building. Exh. 1 at 54. Plaintiffs fail to demonstrate that conclusion is arbitrary or capricious.[10]/

Plaintiffs' second "context" argument asserts DOE should prepare an EIS for the LLNL BSL-3 facility because the DOE has determined to prepare an EIS for a BSL-3 facility at the Los Alamos Nuclear Laboratory in New Mexico. Pl. Br. at 18. This claim fails, however, because the circumstances compelling completion of an EIS for the Los Alamos facility are unrelated to the LLNL facility. As DOE explained in response to public comments, an EA was initially prepared for the Los Alamos facility and a FONSI issued. Exh. 6 at C-4. However, after construction of the facility was complete, DOE determined that the location of the building on fill material on the sloping side of a canyon mandated additional seismic analysis. Id. This issue is unrelated to the impacts of the LLNL BSL-3 facility and does not suggest the DOE was arbitrary or capricious in determining not to prepare an EIS for the LLNL facility.[11]/

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[9]/ This claim, and Plaintiffs' multiple other attempts to relitigate issues and claims resolved in their prior challenge, is barred by the doctrine of res judicata. Res judicata bars relitigation of claims where there is (1) identity of claims; (2) final judgement on the merits; and (3) identity of privity of the parties. Western Radio Serv. v. Glickman, 123 F.3d 1189,1192 (9th Cir.1997) (holding NEPA claim barred by res judicata). All three criteria are met here.

[10]/ To the extent Plaintiffs make their "context" argument in relation the adequacy of the DOE's terrorist release analysis, the DOE took a hard look at the issue, and reasonably concluded that the risk of terrorist attack does not require preparation of an EIS. See supra at 7-14.

[11]/ Plaintiffs' attempt to parlay the need for additional seismic analysis at Los Alamos into a need for additional seismic analysis at LLNL is unavailing. Both this Court and the Court of Appeals have previously upheld DOE's evaluation of seismic issues at LLNL. Exh. 2 at 13; Exh. 3 at 3. There is no basis for relitigation of that claim.

2. An EIS is not needed to address impacts on public health and safety

Plaintiffs assert, based on the alleged risk posed by the potential of a release of a bioagent because of "terrorist attack, accidents, earthquake and fire" that the facility poses significant impacts to public health and safety necessitating an EIS. This claim fails. With regard to a release caused by means other than terrorism – such as accidents or earthquakes – this Court and the Court of Appeals have already found DOE's conclusion that such events will not have a significant impact. Exh. 2 at 12-14 and Exh. 3 at 3-4. There is no basis for relitigation of that claim. With regard to the risk of a release as a result of a terrorist act, the EA conducted a careful evaluation, and reached the reasonable conclusion that an EIS was not needed. See supra at 7-14.

3. Plaintiffs have not demonstrated the existence of "controversy"

Plaintiffs assert that DOE should have prepared an EIS because the possible effects of the LLNL BSL-3 facility on the human environment are highly controversial. Pl. Br. at 20. This claim was considered and rejected in Plaintiffs' prior challenge to the EA. See Exh. 2 at 19-20, Exh. 3 at 3-4. There is no basis for relitigation of this claim here.

4. The effects of the facility are not highly uncertain or unknown

Plaintiffs assert that an EIS was required because the effects "from the operation of the proposed facility are highly uncertain because there is no precedent for the release of pathogenic material from such a facility in the United States." Pl. Br. at 21. In other words, Plaintiffs suggest that because of the *lack* of pathogenic releases from U.S. facilities, the DOE should have prepared an EIS. To the contrary, the long and safe history of BSL-3 operations in the United States is irrefutable proof that the DOE was reasonable in concluding that the operation of the LLNL BSL-3 will not have significant environmental impacts. As the EA explains, the safety records of the hundreds of CDC-registered BSL-3 labs, the experience of the U.S. Army's BDRP labs, and DOE's own experience with microbiology labs all indicate that the operation of the LLNL BSL-3 will not have significant environmental impacts. Exh. 1 at 41-42.[12]/

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[12]/ To the extent Plaintiffs are asserting that DOE erred in relying on the safe history of BSL-3 operations nation-wide, that claim has been reviewed and rejected by this Court and the Court of Appeals and there is no basis for relitigating it here. Exh. 2 at 10-13; Exh. 3 at 3-4.

5. An EIS is not required to consider the BWC

Plaintiffs assert that DOE should have prepared an EIS because the LLNL BSL-3 facility "threatens a violation of the Biological Weapon Convention" (BWC). Pl. Br. at 21. DOE has explained that the LLNL BSL-3 does not violate the BWC. Exh. 6 at C-10. Plaintiffs' disagreement is a policy dispute that falls outside the bounds of NEPA. Metro. Edison Co. v. People Against Nuclear Energy, 460 U.S. 766, 777 (1983) ("Neither the language nor the history of NEPA suggest that it was intended to give citizens a general opportunity to air their policy objections to proposed federal actions. The political process, and not NEPA, provides the appropriate forum in which to air policy disagreements.").

Indeed, Plaintiffs tried and failed to bring this precise claim in their prior case, and this Court, in a decision affirmed by the Court of Appeals, struck all testimony proffered by Plaintiffs on the issues of compliance with the BWC.[13]/ See Dkt 121 at 7. Plaintiffs are unlikely to succeed on their claim that DOE should have prepared an EIS to address potential violations of the BWC.

C. Plaintiffs Have Not Demonstrated a Likelihood of Success on their Claim that the Agency Failed to Supplement the EA.

Plaintiffs' next claim on the merits is that the DOE violated NEPA by failing to supplement the Revised EA to address a laundry-list of allegedly significant new circumstances or information that became available only after the document was issued. Pl. Br. at 22. This claim fails.

NEPA imposes a continuing duty to supplement NEPA analyses in response to "significant new circumstances or information relevant to environmental concerns and bearing on the proposed action or its impacts." 40 C.F.R. § 1502.9(c)(1)(ii).[14]/ To warrant supplementation, the new information or changed circumstances must present a "seriously different picture of the likely environmental harms stemming from the proposed project." Wisconsin v. Weinberger, 745 F.2d

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[13]/ Plaintiffs go so far as to resubmit to this Court the previously stricken testimony. *Compare* current Wheelis Decl. (Pl. Exh. 3) at ¶¶ 18-24 *with* Wheelis Decl. (03-cv-3926 Dkt No. 61-5) at ¶¶ 7, 10, 11, 13, 16, 17, 18. This testimony is no more admissible now than it was in the last case. Plaintiffs also attempt to bolster this claim with an inadmissible hearsay statement from plaintiff Marylia Kelley about the concerns of unidentified diplomats. Pl. Exh. 2 at ¶ 38.

[14]/ While 40 C.F.R. § 1502.9(c)(1)(ii) only addresses the duty to supplement an EIS, it has been applied to EAs by the Ninth Circuit. Idaho Sporting Congress v. Thomas, 137 F.3d 1146, 1152 (9th Cir. 1998).

412, 420 (7th Cir. 1984).[15]/ Thus, a supplemental EIS is not required "every time new information comes to light after the EIS is finalized. To require otherwise would render agency decisionmaking intractable, always awaiting updated information." Marsh, 490 U.S. at 373-74.

Each of the alleged new circumstances identified by Plaintiffs is addressed below:

1. 2005 Shipping Incident

The first allegedly significant new information cited by Plaintiffs is a 2005 incident in which two vials containing *Bacillus anthracis* (anthrax) were improperly closed prior to shipment out of LLNL so that they leaked from their primary containers into the inner packaging of the secondary container, but did not escape tertiary containment. Nobody was injured as a result of the incident, and CDC and DOT inspected LLNL's select agent program and approved of improvements made to address the causes of the incident. Exh. 1 at 56-57.

This is not a case of new information which became available only after the Revised EA was issued. As Plaintiffs concede, the incident was addressed in the draft Revised EA which was issued for public comment on May 11, 2007. After the close of the comment period, Plaintiffs wrote DOE to complain about the lack of detail with which the incident was discussed. See Pl. Exh. 2 at ¶ 28. In response to Plaintiffs' comment, the DOE presented a more detailed discussion of the 2005 shipping incident in the final Revised EA. Exh. 6 at C-26; Exh. 1 at 56-57.

Plaintiffs' claim therefore, is not that DOE failed to address the 2005 shipping incident in the final Revised EA, but that the DOE was required to recirculate the final Revised EA for additional public comment on the more detailed discussion of the incident. This claim fails. First, NEPA does not require that EAs be circulated for public comment in the first instance. Bering Strait Citizens v. U.S. Army Corps of Eng'rs, 511 F.3d 1011, 1025 (9th Cir. 2008).[16]/ Just as DOE was not obligated to circulate the draft EA for public comment, it was also not required to recirculate the

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[15]/ See also Sierra Club v. Froehlke, 816 F.2d 205, 210 (5th Cir. 1987) ("[N]ot every new circumstance, however small, requires filing a SEIS; the new circumstance must present a *seriously* different picture of the environmental impact of the proposed project from what was previously envisioned") (emphasis in original).

[16]/ Nor do DOE regulations require that EAs be circulated for public comment. See 10 C.F.R. § 1021.301(d) (obligating DOE to circulate draft EAs only to host tribes and host states).

final EA. Unsurprisingly, Plaintiffs cite no caselaw for the proposition that the addition of detail to the Final EA of an issue described in the draft –in response to public comments on the draft EA – requires that the final EA be circulated for public comment. Indeed, the only caselaw of which Defendants are aware holds precisely the opposite. See Biodiversity Conservation Alliance v. U.S. BLM, 404 F.Supp.2d. 212, 220 (D.D.C. 2005) (noting that "Plaintiffs have not cited any binding authority to support their argument that the regulations require an agency to solicit supplemental public comments when there are changes to the proposed action before the EA has been issued," and holding that an increase in project area did not require agency to solicit supplemental public comments on final EA).

Finally, even taking the 2005 incident as new information, nothing in the more detailed description of the 2005 shipping incident "affect[s] the environment in a significant manner or to a significant extent not already considered," Marsh, 490 U.S. at 374, or "provides a *seriously* different picture of the environmental landscape." Nat'l Comm. for the New River v. F.E.R.C., 373 F.3d 1323, 1330 (D.C. Cir. 2004) (emphasis in original). The transportation analysis in the EA is reasonably based on the safe history of the transportation of *thousands* of shipments annually of hundreds of *tons* of infectious materials. A single transportation incident, in which nobody was injured and there was no public release, does not provide a seriously different picture of impacts of the proposed facility.[17]/ Indeed, the fact that the incident was reported to CDC, and that CDC and DOT inspected LLNL's shipping protocols and approved of the improvements made by the lab, illustrates that shipping of BSL-3 agents is subject to robust oversight and effective controls.

2. Information regarding safety and security of BSL-3 facilities

Plaintiffs next assert that DOE was required to supplement the EA to address a newspaper article from October 2, 2007, which reports on incidents at BSL-3 and BSL-4 facilities around the country. Pl. Br. at 26. Plaintiffs contend that article "undercuts" DOE's conclusion that laboratory staff are unlikely to acquire infection during the operation of the facility, and that transportation

[17]/ Plaintiffs previously challenged DOE's evaluation of the risks of transporting BSL-3 agents. Both this Court and the Ninth Circuit upheld that analysis. Exh. 2 at 8-10; Exh. 3 at 3-4. They may not relitigate that issue here.

related incidents are unlikely to increase. Id.[18]/

As noted above, see supra at 4-5, the DOE carefully analyzed the safety of lab operations, and based its conclusion that the risk of laboratory infection in the facility was no different than at other BSL-3 facilities and was not significant based on the nearly 30-year history of safe operations of BSL-3 labs in the country. Nothing in the October 2007 article makes the DOE's conclusion –which is based on *decades* of experience– arbitrary or capricious. Nor does the article demonstrate a "seriously different picture of the likely environmental harms stemming from the proposed action." Wisconsin v. Weinberger, 745 F.2d at 420.

3. GAO Report on the Increase in BSL-3 Facilities

Plaintiffs next point to a Governmental Accountability Office (GAO) Report which found a "major proliferation" of BSL-3 and BSL-4 facilities in the United States. Pl. Br. at 27. The GAO report does not constitute new information. As Plaintiffs themselves concede, the DOE considered the GAO report in preparing the Revised EA. Id. Thus Plaintiffs' complaint cannot be that the GAO report constitutes new information requiring supplementation of the Revised EA, but rather a disagreement over the weight given the Report in the Revised EA. In this regard, Plaintiffs allege that the expansion in the number of BSL-3 facilities "may obviate the need" for a BSL-3 facility at LLNL. Pl. Br. at 27. This assertion fails because it rests on the erroneous assumption that the only reason for an on-site BSL-3 facility is the lack of availability of off-site facilities. To the contrary, as explained in the EA, using off-site facilities does not serve the Agency's purpose and need for a multitude of reasons: the chances of cross-contamination and degradation of samples is increased by the excessive handling and transportation required by using off-site labs; third party facilities cannot uniformly meet the information and physical security requirements needed by the DOE and DHS; off-site facilities may not be able to provide the "chain of custody" requirements for federal projects; and it is not cost effective to use off-site facilities when the human expertise is available

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[18]/ Plaintiffs also cite a list of incidents proffered in the declaration of Edward Hammond. The majority of the incidents, however, occurred before May 2007 when the revised EA was circulated for public comment. Information available to Dr. Hammond during the public comment period should have been submitted to the Agency during that time, and cannot now form the basis for a "new" information claim. Dep't of Transp. v. Public Citizen, 541 U.S. 752, 765 (2004).

on-site. See Exh. 1 at 7; Exh. 6 at C-28, C-29; Exh. 5 at ¶ 6. Thus, while the lack of availability of other facilities is one factor contributing to the need for a BSL-3 facility on-site, there are numerous other factors which are not impacted by the increase in off-site facilities, and the increase in the number of BSL-3 facilities nation-wide does not suggest that the DOE was arbitrary and capricious in its determination that it needs a BSL-3 facility on-site at LLNL.

4. Congressional Hearing

Plaintiffs also list as a separate "new circumstance" an October 2007 Congressional hearing at which the GAO report addressed above was presented. As noted above, nothing in the GAO report demonstrates that the conclusions reached by DOE in the EA were arbitrary and capricious. Plaintiffs point to nothing in the Congressional hearing reiterating that report which demonstrates a "seriously different picture of the likely environmental harms stemming from the proposed action." Wisconsin v. Weinberger, 745 F.2d at 420.

5. Leitenberg Report

Finally, Plaintiffs assert that a December 2005 research paper by Milton Leitenberg which argues "the U.S. biodefense research program appears to be drifting into violation" of the Biological Weapons Convention (BWC) constitutes significant new information requiring supplementation of the EA. Pl. Br. at 28. This claim fails. First, and most simply, the December 2005 report does not constitute new information. The draft Revised EA was circulated for public comment in May 2007 –almost two years after the cited report. The Revised EA explains that the BSL-3 facility will comply with the BWC (Exh. 1 at 18) and the DOE addressed concerns about compliance with the BWC that were submitted during the comment period. Exh. 6 at C-10 to C-11. To the extent that Plaintiffs believe that this specific report adds significantly to that discussion, they had the ability and the obligation to present the report to DOE during the public comment period. By failing to do so, Plaintiffs have waived their right to pursue the issue in this Court. Dep't of Transp. v. Public Citizen, 541 U.S. 752, 765 (2004) (holding that respondent forfeited particular challenges to an agency action when it failed to raise those challenges in the public comment period); Universal Health Serv. Inc., v. Thompson, 363 F.3d 1013, 1019 (9th Cir. 2004) (holding "a party's failure to make an argument before the administrative agency in comments on a proposed rule barred it from

raising that argument on judicial review").

Second, even if the Leitenberg Report constitutes new information, it does not compel supplementation of the EA. As noted above, see supra at 17-18, the assertion that operation of the LLNL BSL-3 facility will violate the BWC is a political policy dispute beyond the ambit of the environmental impacts to be addressed under NEPA. Metropolitan Edison, 460 U.S. at 777.

D. DOE Was Not Required to Make the LLNL BSL-3 FONSI Available for Public Review Before Implementing the Project.

Plaintiffs assert that the DOE was obligated by CEQ regulations to make the FONSI available for public review for 30 days before implementing the project, because "[t]he nature of the proposed action is one without precedent." Pl. Br. at 29 (citing 40 C.F.R. § 1501.4(e)(2)(ii)). Notwithstanding the 1,350 existing BSL-3 facilities, Plaintiffs attempt to portray the LLNL BSL-3 facility as "without precedent" by emphasizing that it is the first such facility to be proposed by the DOE. Pl. Br. at 30. This argument misstates the law.

The question of whether a proposed action is "without precedent"under 40 C.F.R. § 1501.4(e)(2)(ii), turns on the nature of the *environmental* impact of the action rather than the agency with jurisdiction over the project. For example, in Alliance to Protect Nantucket Sound, Inc. v. U.S. Dep't of Army, 288 F. Supp. 2d 64, 78-79 (D. Mass. 2003), plaintiffs alleged the Corps' approval of a privately owned data tower in waters under federal jurisdiction was without precedent because the only other data towers in the area were in State waters and publicly owned. The district court rejected this contention: "From an environmental perspective, however, these differences are irrelevant. Neither the location nor the nature of ownership of Cape Wind's data tower render its environmental impacts different from those of the Martha's Vineyard tower." Id. at 79 n.107. The First Circuit affirmed, emphasizing that "[t]he CEQ regulations, however, are designed to address environmental impact. . . . [and] we can see nothing unprecedented about the way this data tower will impact the environment. 398 F.3d 105, 115 (1st Cir. 2005).

Here there is no difference between the environmental impacts of the LLNL BSL-3 facility and the 1,350 other facilities nation-wide, and consequently DOE was not required to make the FONSI available for public review before implementing the project.

VI. THE BALANCE OF EQUITIES STRONGLY MILITATES AGAINST ISSUANCE OF A PRELIMINARY INJUNCTION

A. Plaintiffs Have Not Demonstrated They Will Suffer Irreparable Injury.

Plaintiffs assert irreparable injury in the form of the risk to the public health posed by the release of a pathogen from the LLNL BSL-3 facility. Pl. Br. at 31. Plaintiffs do not explain why the risks of such a release at this facility are of greater concern than the risk from any of the BSL-3 labs around the country in operation every day.

As set forth above, the DOE has taken a hard look at the environmental impacts of the proposed facility and reached the reasonable conclusion that – particularly when considered in the context of the hundreds of other facilities in operation, and in light of the physical security available at LLNL – this single facility will not have a significant impact on the environment.

The possibility of an event resulting in the accidental release that Plaintiffs fear rests on a chain of speculation too attenuated to justify preliminary injunctive relief. For example: a terrorist attack or earthquake would have to occur; AND the incident would have to breach multiple layers of containment; AND the breach would have to occur in a manner that did not generate sufficient heat to innoculate the bioagents or release solvents which would kill bioagents; AND the incident would have to damage the negative air pressure system which otherwise would draw air into the structure instead of allowing it to escape unfiltered; AND upon release, biological agents would have to survive external environmental conditions which would quickly innoculate and dilute the agents to the point that they would not pose a public health hazard.

Thus, the risk that Plaintiffs claim as an irreparable harm is based on a chain of events, each of which is exceedingly unlikely to occur. Such a speculative possibility cannot constitute an irreparable harm that would justify injunctive relief. Caribbean Marine Serv., 844 F.2d at 675 (finding that plaintiffs' injuries "too remote and speculative to constitute irreparable injury" where "[m]ultiple contingencies must occur before their injuries would ripen into concrete harms.").[19]/

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[19]/ Moreover, to justify a preliminary injunction, Plaintiffs must demonstrate that they face a risk of this speculative chain of events occurring *during the adjudication of this case* on the merits. 11A Wright & Miller § 2948.1 ("Perhaps the single most important prerequisite for the issuance of a preliminary injunction is a demonstration that if it is not granted the applicant is likely to suffer

B. An Injunction Will Harm the Public Interest

In exercising its discretion to determine whether an preliminary injunction is appropriate, the Court "should pay particular regard" to the public interest. Weinberger v. Romero-Barcelo, 456 U.S. 305, 312 (1982). In this case, the public interest strongly disfavors an injunction. As explained in the attached declarations of Jeffrey Stiefel and Susan Elizabeth George, the LLNL BSL-3 facility will perform critical work to improve the Nation's ability to detect and respond to the threat of terrorism using biological agents, and accordingly, halting operations at the facility would directly and adversely impact national security. Exhs. 10 and 11.

C. An Injunction Will Harm LLNL's Biological Security Program

In contrast to Plaintiffs' entirely speculative harm, an injunction poses a concrete harm to LLNL. LLNL is in the midst of the annual funding proposal cycle and is applying for funding to perform BSL-3 work for the next year. See Exh. 5 at ¶ 4. Even a short-term injunction would result in the withdrawal of current proposals, forcing LLNL to wait another year to request funding. A loss of funding for this year would translate into the loss of jobs for up to eight people. Id. at ¶ 6. This delay could have a long term impact on LLNL's ability to retain and recruit staff, because without an operational BSL-3 facility, LLNL lacks a basic tool needed to conduct research in this field, and qualified researchers may other facilities to pursue their research careers. Id. at ¶ 5.

VII. CONCLUSION

For the reasons set forth above, Plaintiffs' motion for a preliminary injunction halting ongoing operations at the LLNL BSL-3 facility should be denied.

Dated this 26th day of March, 2008.

Respectfully submitted,
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irreparable harm before a decision on the merits can be rendered").